

List of Subjects

26 CFR 1.701-1 through 1.771-1 Part 1

Income taxes, Partnerships.

26 CFR 1.1361-0A through 1.1388-1

Income taxes, Small business,
Subchapter S corporation, Cooperatives.

Lawrence B. Gibbs,

Commissioner of Internal Revenue.

[FR Doc. 88-4450 Filed 3-1-88; 8:45 am]

BILLING CODE 4830-01-M

**ENVIRONMENTAL PROTECTION
AGENCY****40 CFR Part 180**

[PP 6E3409/P444; FRL-3337-1]

Terbufos; Proposed Tolerance**AGENCY:** Environmental Protection
Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: This document proposes that a tolerance be established for combined residues of the insecticide/nematicide terbufos and its cholinesterase-inhibiting metabolites in or on the raw agricultural commodity (RAC) bananas. This regulation to establish the maximum permissible level for residues of the insecticide/nematicide was requested by the American Cyanamid Co.

DATE: Comments, identified by the document control number [PP 6E3409/P444], should be received by April 1, 1988.

ADDRESS: By mail, submit written comments to:

Information Services Branch, Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

In person, bring comments to: Rm. 236, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 236 at the address

given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail:

William H. Miller, Product Manager (PM) 16, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 222, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-557-2600.

SUPPLEMENTARY INFORMATION: The American Cyanamid Co., P.O. Box 400, Princeton, NJ 08540, has submitted Pesticide Petition No. 6E3409, requesting that EPA pursuant to section 408(d)(1) of the Federal Food, Drug, and Cosmetic Act, propose the establishment of a tolerance for the combined residues of the insecticide/nematicide terbufos (S-[[[1,1-dimethylethyl]thio]methyl]-O,O-diethyl phosphorodithioate) and its cholinesterase-inhibiting metabolites in or on the RAC bananas at 0.025 part per million (ppm).

The data submitted in the petition and other relevant material have been evaluated. The pesticide is considered useful for the purpose for which the tolerance is sought. The toxicological data considered in support of the proposed tolerance include:

1. A 1-year dog feeding study with a lowest-observable-effect level (LOEL) of 0.015 milligram/kilogram/day (mg/kg/day) based on the inhibition of plasma cholinesterase activity.

2. A 4-week dog plasma cholinesterase study with a no-observable-effect level (NOEL) of 0.00125 mg/kg/day based on the inhibition of plasma cholinesterase activity.

3. A 1-year rat feeding study with a no-observable-effect level (NOEL) of 0.5 ppm (0.025 mg/kg) based on the inhibition of plasma and brain cholinesterase activity.

4. An 18-month mouse oncogenicity study with no oncogenic effects observed at dosage levels up to and including 12.0 ppm (1.8 mg/kg/day), which was the highest level tested.

5. A 2-year rat oncogenicity study with no oncogenic effects observed at doses up to and including 2.0 ppm (0.10 mg/kg/day).

6. A three-generation rat reproduction study with a NOEL a 0.25 ppm (0.0125 mg/kg) for reproductive effects.

7. A rat teratology study with a NOEL of 0.1 mg/kg/day for developmental toxicity.

8. An acute delayed neurotoxicity study in chickens, which was negative

for neurotoxic effects under the conditions of the study (highest dose tested was 40 mg/kg).

9. Several mutagenicity tests which were all negative. These include a dominant lethal study in rats; an acute *in vivo* cytogenetic assay in rats; an Ames test including metabolic activation; a DNA repair chromosomal aberration (CHO cells); CHO/HGPRT mutation assay; and a rat hepatocyte primary culture/DNA repair test.

A rabbit teratology study was submitted but was classified as supplementary. Although supplementary, the study results did not show any evidence of developmental toxicity. A new rabbit teratology study is needed to fulfill the regulatory requirements.

Based on the plasma cholinesterase inhibition (ChE) NOEL as defined in a 4-week dog study (0.00125 mg/kg/day) and using a safety factor of 10, the acceptable daily intake (ADI) for humans is 0.000125 mg/kg/day.

The current established tolerances for residues of terbufos and its cholinesterase-inhibiting metabolites result in theoretical maximum residue contribution (TMRC) of 0.000047 mg/kg/day and utilize 37.332 percent of the ADI. As a result of this proposed regulation, the TMRC will be increased to 0.000052 mg/kg/day and 41.9464 percent of the ADI will be utilized. No feed items are involved; therefore, it is expected that no secondary residues in meat, milk, poultry, and eggs will result from the use of the pesticide on bananas.

The metabolism of the insecticide/nematicide is adequately understood, and an analytical method, gas chromatography with a flame photometric detector, is available in the Pesticide Analytical Manual, Vol. II, for enforcement purposes.

Because of the lack of a teratology study in a second species, the Agency is limiting the period of time that the proposed regulation is to be in effect. Should the Agency find that the new rabbit teratology study is acceptable, it will reassess the tolerance for bananas and, if appropriate, will establish a permanent tolerance for this commodity. There are no regulatory actions pending against continued registration of the insecticide, and no other considerations are involved in establishing the tolerance.

The pesticide is considered useful for the purpose for which the tolerance is sought. Based on the above information and data, the Agency concludes that the establishment of the regulation would protect the public health. Therefore, it is

proposed that 40 CFR 180.352 be amended as set forth below.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number [PP 6E3409/P444]. All written comments filed in response to this petition will be available in the Program Management and Support Division, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Office of Management and Budget has exempted this regulation from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new food or feed additive levels, or conditions for safe use of additives or raising such food or feed additive levels, do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the *Federal Register* of May 4, 1981 (46 FR 24945).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: February 18, 1988.

Edwin F. Tinsworth,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR Part 180 be amended as follows:

1. The authority citation for Part 180 continues to read as follows:

Authority: 21 U.S.C. 346a.

2. Section 180.352 is amended by designating the existing text as paragraph (a) and by adding new paragraph (b), to read as follows:

§ 180.352. Terbufos; tolerances for residues.

(a) ***

(b) A temporary tolerance to expire [date 24 months after effective date of final rule] is established for combined residues of the insecticide/nematicide terbufos [S-[[[1,1-dimethylethyl]thio]methyl]-O,O-diethyl phosphorodithioate] and its cholinesterase-inhibiting metabolites in or on the raw agricultural commodity as follows:

Commodity	Parts per million
Bananas.....	0.025

[FR Doc. 88-4612 Filed 3-1-88; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 413

[BERC-408-P]

Medicare Program; Payment for Kidneys Sent to Foreign Countries or Transplanted in Non-Medicare Beneficiaries

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: These proposed regulations would exclude the costs associated with kidneys sent to foreign countries or transplanted in non-Medicare recipients from Medicare payments made to organ procurement agencies.

In addition to reducing Medicare expenditures by eliminating Medicare subsidization of the costs of kidneys sent to foreign countries or transplanted in non-Medicare recipients, we intend these regulations to increase the availability of kidneys to Medicare beneficiaries who are suitable transplant candidates. This could result in medical and social benefits for transplanted patients, and reductions in Medicare expenditures because kidney transplantation is more cost-effective than maintaining beneficiaries on kidney dialysis.

DATE: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5:00 p.m. on May 2, 1988.

ADDRESS: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BERC-408-P, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC, or
Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

In commenting, please refer to file code BERC-408-P. Comments received timely will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: 202-245-7890).

FOR FURTHER INFORMATION CONTACT: Mark Horney, (301) 597-6939.

SUPPLEMENTARY INFORMATION:

I. Background

The Social Security Amendments of 1972 (Pub. L. 92-603) extended Medicare coverage to individuals with end stage renal disease (ESRD) who require dialysis or transplantation. Section 1881 of the Social Security Act (the Act) provides for Medicare payment for kidney transplantation. One of the major components of kidney transplantation is the retrieval of organs through an organ procurement agency (OPA). An OPA, whether independent or hospital-based, is defined in Medicare regulations (42 CFR 405.2102) as an organization that performs or coordinates the performance of all the following services: (1) Harvesting of donated kidneys; (2) preservation of donated kidneys; (3) transportation of donated kidneys; and (4) maintenance of a system to locate prospective recipients for harvested organs.

Since the inception of the ESRD program, OPAs have harvested kidneys from donors. Once kidneys are retrieved, the OPA searches for and identifies acceptable recipients and coordinates transporting these kidneys to other OPAs, transplant centers or foreign countries. The OPA places kidneys with a transplant organization based on the best possible match of tissue type, blood type, etc., as well as consideration for cold ischaemic time (the amount of time a kidney has been outside the body and packed on ice), transportation distance, etc.

The Medicare program pays separately for kidney acquisition services and kidney transplantations. The OPA bills each of the organizations that receive kidneys a standard acquisition charge for each kidney. The standard acquisition charge reflects the cost of removing, preserving, and transporting a kidney, etc., and does not include a charge for purchasing the kidney. While a hospital-based OPA develops its own charge, an independent OPA's charge is developed by its Medicare fiscal intermediary based on

the OPA's costs of operating. These standard acquisition charges become the interim payment for each OPA. The OPA submits its costs of operating on a cost report at the end of its fiscal year. The cost report details both the costs of procuring kidneys and the amounts received from the shipment of kidneys to other OPAs, transplant centers, military hospitals, veterans hospitals, and foreign countries. The net difference between the total cost and the total amount received represents the amount due to or from the intermediary.

The Medicare program has always paid the total costs of OPAs because we assumed that all kidneys procured were for Medicare beneficiaries. However, we now realize that this assumption is incorrect and that technology has allowed a significant number of kidneys to be shipped overseas. Since the Medicare program has been paying the cost of procuring kidneys shipped overseas or transplanted into non-Medicare beneficiaries, we believe that some action needs to be taken. It is now necessary to amend the regulations in

order to effectuate the statutory principles embodied in section 1861(v)(1)(A) of the Act. Section 1861(v)(1)(A) of the Act requires that the cost of services be borne by the appropriate payor. Accordingly, the cost associated with the kidneys not used by Medicare beneficiaries must be borne by the responsible individual or third party payor. Medicare is precluded from paying any costs associated with kidneys not used by Medicare beneficiaries.

II. Current Transplantation Practices

Recent advances in transplantation technology and immunotherapy are increasing the use and success rates of kidney transplants. With respect to cadaveric kidney transplants, the improvements in patient outcomes have been striking. One-year patient survival rates are now averaging about 95 percent. One-year graft survival rates are averaging between 70 and 80 percent, with some transplant centers reporting results well above 80 percent. In contrast, in the late 1970s one-year

cadaveric kidney graft survival rates were averaging only a little over 50 percent.

A major factor behind these gains has been the widespread introduction in November 1983 of cyclosporine, a powerful immunosuppressive drug. Studies have shown that the use of cyclosporine has been responsible for increasing one-year graft survival rates by anywhere from 8 to 12 percent and has been particularly valuable for patients who are highly-sensitized (that is, have a high level of preformed antibodies) and who have received a kidney with a low antigen match.

Accordingly, there has been a considerable increase in the number of kidney transplants occurring in the U.S. From 1980 to 1985, the number of transplants increased from 4,697 to 7,695, an increase of 63.8 percent. During this period, cadaveric transplants increased from 72.9 percent of the total to 75.6 percent. The following table shows the number of transplants for each year since 1980.

KIDNEY TRANSPLANTS

Year	Living	Cadaveric	Total	Percent cadaveric	Annual increase in transplants (percent)
1980	1,275	3,422	4,697	72.8	
1981	1,458	3,425	4,883	70.2	4.0
1982	1,677	3,681	5,358	68.7	9.7
1983	1,784	4,328	6,112	70.8	14.1
1984	1,704	5,264	6,968	75.5	14.0
1985	1,876	5,819	7,695	75.6	10.4

While the number of transplants rose, the demand for transplants increased even faster. From 1980 to 1985, the number of individuals awaiting kidney transplants across the country jumped from 5,072 to 9,791, an increase of 93 percent. As of December 31, 1985, there were 9,791 individuals awaiting kidney transplants. We estimate that over 8,000 individuals will receive kidney transplants in 1986. However, even with 8,000 transplants, the waiting list will increase to near 10,000 individuals.

The Department's Office of the Inspector General (OIG) undertook a comprehensive study to help the Department and other interested parties gain a better understanding of the effectiveness, efficiency, and equity of organ acquisition practices in this country. OIG released its first report in August 1986 (Control No. P-01-86-00074). The findings detailed in these proposed regulations are in agreement with the OIG report. One of the

recommendations contained in the OIG report was that—

HCFA should undertake efforts to help ensure that kidneys are not exported to other countries unless it has been determined that no suitable U.S. recipient can be found. Further, when kidneys are sent to other countries, HCFA should prohibit Medicare reimbursement for any of the acquisition costs of those kidneys. (Page 18)

OIG estimated that 200 to 250 kidneys were exported from the United States in 1985. In these instances, U.S. transplant centers or independent OPAs send kidneys to other countries for transplantation. OPAs have regularly sent kidneys overseas when they could not place kidneys among their member organizations. In addition, kidneys are exported by individual transplant centers that have developed working relationships with foreign surgeons interested in U.S. cadaveric kidneys.

Typically, the exported kidneys have been older ones that have been removed from cadaveric donors and that, after 40

or more hours cold ischaemic time, still have not been matched with an appropriate recipient in this country. (Reasons for the excessive time could be a large number of highly sensitized patients, inability to obtain an acceptable match, or excessive transportation times.) Many foreign surgeons have been eager to receive and transplant such kidneys. Foreign transplant centers have had good success rates with kidneys averaging 60 to 70 hours cold ischaemic time. As a result, exportation of these kidneys has often been viewed as a way to use a kidney that would otherwise be discarded. Nonetheless, the practice of exporting kidneys has become increasingly visible and controversial as the demand for kidneys in this country has intensified.

III. Rationale for Program Change

The estimated 200 to 250 cadaveric kidneys that were exported in 1985 were

equivalent to 3.4 to 4.3 percent of all cadaveric kidneys transplanted in this country. If these kidneys were not exported, some, given their advanced age, would have been wasted. However, we assume that with effective pooling and sharing of cadaveric kidneys, it would have been feasible to use a number of these kidneys for transplantation in this country. Therefore, exporting cadaveric kidneys is likely to lessen the opportunity for beneficiaries to receive available kidneys and benefit medically and socially from transplantation. Transplantation affords the recipient the likelihood of a healthier and more independent life. Most importantly, transplantation may save or prolong the life of the recipient. In the current environment, when the demand for kidneys is greater than the supply, any exported kidney may potentially result in a beneficiary being denied that kidney and may increase the waiting time for all U.S. citizens awaiting transplantation.

To the extent exported kidneys could have been transplanted in Medicare beneficiaries, exportation also results in increased Medicare costs. Over time, transplantation costs less than maintaining a patient on dialysis. Thus, based on 1985 data for each transplant opportunity lost to a Medicare beneficiary on a transplant waiting list in 1985, the Medicare program would spend an estimated \$62,000 for the marginal cost of dialysis over a five-year period.

Kidneys sent to military institutions have been paid for by those institutions. Kidneys transplanted into other non-Medicare beneficiaries have been paid for by those individuals or their third-party payors. The Medicare program has always assumed that the remaining kidneys were for Medicare beneficiaries. However, we now realize that this assumption is incorrect and that technology has allowed a significant number of kidneys to be shipped overseas. Since the Medicare program has been paying the cost of procuring kidneys shipped overseas, we believe that some action needs to be taken. It is now necessary to amend the regulations in order to effectuate the statutory principles embodied in section 1861(v)(1)(A) of the Act. In accordance with section 1861(v)(1)(A) of the Act, the cost associated with kidneys not used by Medicare beneficiaries should be borne by the recipient of the organ or the insurer. Kidneys sent overseas

should be paid for by the foreign transplant center. Section 1861(v)(1)(A) precludes Medicare from paying any costs associated with kidneys not used by Medicare beneficiaries.

Currently, the Medicare program reimburses OPAs for the net reasonable costs associated with procuring all kidneys including those sent to foreign countries. For those kidneys sent overseas, transportation costs are not paid by Medicare even if such costs are not paid for by the foreign receiving center. If a foreign country pays the cost of kidney acquisition, these payments are offset against the total costs and Medicare payment is reduced; however, in the great majority of cases, kidney acquisition costs have not been paid by the foreign center. In the past there has not been an incentive for foreign centers to reimburse OPAs for the cost of U.S. organs shipped overseas.

IV. Proposed Regulation Changes

We would add a new regulation section (42 CFR 413.179) that would apply to all OPAs and any transplant center that claims kidney acquisition costs on worksheet D-6 of the Hospital Cost Report (HCFA-2552). (42 CFR Part 413 was established on September 30, 1986 at 51 FR 34790.) We would require that kidneys sent to foreign transplant centers or transplanted in non-Medicare recipients be excluded from Medicare payments to OPAs. OPAs that send kidneys to foreign countries would have to ensure that they receive the full amount from the foreign transplant centers for procurement and transportation of the kidneys. We would require OPAs to separate costs associated with kidneys that are sent to foreign countries or transplanted in non-Medicare recipients from Medicare allowable costs prior to final settlement by the Medicare fiscal intermediary. The fiscal intermediary would compute the ratio of the number of kidneys used for Medicare beneficiaries to the total number of kidneys used and adjust the costs for kidneys sent to foreign countries or transplanted in non-Medicare recipients. For this purpose, kidneys furnished to other OPAs or transplant centers in the United States would be assumed to be used for transplants in Medicare beneficiaries. However, any costs associated with kidney transplants for non-Medicare recipients that are performed in transplant centers would be excluded from total costs of the transplant centers, thereby excluding them from

Medicare reimbursement. (The Medicare program will continue to pay for its proportionate share of costs incurred in procuring kidneys that were not transplanted.)

We issued contractor operating manual instructions in January of this year that require all OPAs to maintain a log detailing placement efforts. This is intended to document the efforts that OPAs are making to place kidneys in beneficiaries before shipping kidneys overseas.

We have detailed below two examples using identical data that show the method of reimbursing OPAs for kidney acquisition costs under the current and proposed methodologies.

DATA

Total Usable Kidneys.....	120
Total Foreign Kidneys.....	20
Total Military Kidneys.....	20
Total Cost.....	\$1,200,000
Foreign Revenue.....	\$25,000
Military Revenue \$200,000	
Payments from Other OPAs or Transplant Centers.....	\$850,000

Note.—Included in the \$1,200,000 total cost are costs associated with nonviable (unusable) kidneys. The Medicare program will continue to pay for its proportionate share of costs incurred in procuring kidneys that were not transplanted.

Current Methodology

Under the current methodology, the total cost of procuring kidneys is reduced by the revenue received and the balance is the amount due to or from the Medicare fiscal intermediary. Using the above data in the computation below, the amount the Medicare fiscal intermediary would pay the OPA would be \$125,000 on final settlement.

Total Cost.....	\$1,200,000
Less Military and Foreign Revenue.....	—225,000
Subtotal.....	975,000
Less Payments from Medicare OPAs and Transplant Centers.....	—850,000
Balance Due OPA from Intermediary.....	\$125,000

Proposed Methodology

Under the proposed methodology, an OPA's total cost for all kidneys would be reduced by the costs associated with kidneys transplanted in non-Medicare beneficiaries or sent to foreign countries regardless of income received from these sources. Using the above data in the computation below, the amount the OPA would pay the Medicare program at the end of the OPA's fiscal year is \$46,000.

Step 1—Compute the Medicare Ratio

$$\begin{array}{rcl} \text{(Medicare Usable Kidneys)} & = & \text{(Total Usable Kidneys)} - \text{(Total Foreign \& Military Kidneys)} \\ 80 & = & 120 - 40 \end{array}$$

$$\begin{array}{rcl} \text{Medicare Ratio} & = & \frac{\text{Medicare Usable Kidneys}}{\text{Total Usable Kidneys}} \\ .67 & = & \frac{80}{120} \end{array}$$

Step 2—Compute Medicare Allowable Costs

Total Cost (Net of transportation costs for exported kidneys.....)	\$1,200,000
Multiplied by Medicare Ratio (.67).....	X .67
Medicare Costs.....	804,000
Less Payments from OPAs and Transplant Centers for Medicare Kidneys ..	-850,000
Balance Due Medicare Program from OPA.....	\$(46,000)

The revised system would result in reduced payments to OPAs since the Medicare program would no longer subsidize the costs of kidneys that are sent to foreign countries or transplanted in non-Medicare beneficiaries. In the above example, Medicare payments would decrease from \$975,000 under the current system to \$804,000 under the proposed system. OPAs would have to recoup costs of kidneys from the receiving non-Medicare beneficiaries or foreign countries. Accordingly, despite the reduction in Medicare expenditures, there should be only a minimal effect on any OPA.

V. Regulatory Impact Statement

Executive Order 12291 (E.O. 12291) requires us to prepare and publish an initial regulatory impact analysis for any proposed regulations that are likely to meet criteria for a "major rule." A major rule is one that would result in:

- (1) An annual effect on the economy of \$100 million or more;
- (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or any geographic regions; or
- (3) significant adverse effects on competition, employment, investment, productivity, innovation or on the ability of United States-based enterprises to

compete with foreign-based enterprises in domestic or export markets.

In addition, consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612), we prepare and publish an initial regulatory flexibility analysis for proposed regulations unless the Secretary certifies that the regulations would not have a significant impact on a substantial number of small entities. For purposes of the RFA, we consider OPAs to be small entities.

Currently, there are approximately 120 OPAs, slightly more than half of which are independent (that is, not hospital-based). We expect that the revised system will result in reduced payments to some OPAs and result in some program savings, estimated to be approximately \$1 million for the first full year of implementation of this regulation. We expect that most OPAs would experience some reductions in Medicare revenues, but that these reductions would not be substantial unless an OPA were providing a disproportionately large number of kidneys to foreign countries. This proposal would have an adverse effect on total revenue only if an OPA were unable to obtain payment for the costs associated with kidneys transplanted into non-Medicare beneficiaries or sent to foreign countries. However, we do not believe this would be likely. Ordinarily, OPAs would be able to recover their costs not reimbursed by Medicare from non-Medicare beneficiaries and foreign transplant centers.

As discussed above, one potential consequence of this change would be an increase in the number of kidneys available for Medicare beneficiaries who need transplants. To the extent that this potential is realized, there would be resulting reductions in Medicare expenditures since patients could be transferred from more costly dialysis to less costly transplantation. These savings would be contingent on matching kidneys with appropriate recipients within a time period considered acceptable. To some extent this may depend on whether U.S. surgeons accept kidneys with a longer cold ischaemic time for transplantation. Thus, the savings are not estimable.

We have determined that this regulation does not meet the criteria of

E.O. 12291 and does not require an initial regulatory impact analysis. Also, we have determined, and the Secretary certifies, that these proposed regulations would not have a significant economic impact on a substantial number of small entities. Therefore, an initial regulatory flexibility analysis has not been prepared.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any proposed rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 50 beds located outside a metropolitan statistical area. We have determined, and the Secretary certifies, that this proposed regulation would not have a significant economic impact on the operations of a substantial number of small rural hospitals.

VI. Information Collection Requirements

These regulations do not contain information collection requirements that are subject to approval by the Executive Office of Management and Budget under the Paperwork Reduction Act of 1980.

VII. Response to Comments

Because of the large number of comments we receive on proposed regulations, we cannot acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments received timely and respond to the major issues in the preamble to that rule.

VIII. List of Subjects in 42 CFR Part 413

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Nursing homes, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set out in the preamble, Title 42, Part 413 is proposed to be amended as follows:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES

1. The authority citation for Part 413 continues to read as follows:

Authority: Secs. 1102, 1122, 1814(b), 1815, 1833(a), 1861(v), 1871, 1881, and 1886 of the Social Security Act as amended (42 U.S.C. 1302, 1320a-1, 1395f(b), 1395g, 1395l(a), 1395x(v), 1395hh, 1395rr, and 1395ww).

2. Section 413.179 is added to Subpart H to read as follows:

§ 413.179 Organ procurement agencies' (OPAs) or transplant centers' costs for kidneys sent to foreign countries or transplanted in non-Medicare beneficiaries.

An OPA's or transplant center's total costs for all kidneys will be reduced by the costs associated with procuring kidneys sent to foreign transplant centers or transplanted in non-Medicare beneficiaries. Both independent and hospital-based OPAs, as defined in § 405.2102 of this title, must separate costs for procuring kidneys that are sent to foreign transplant centers and kidneys transplanted in non-Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare fiscal intermediaries. Medicare costs will be based on the ratio of the number of usable kidneys transplanted into Medicare beneficiaries to the total number of usable kidneys applied to reasonable costs.

(Catalog of Federal Domestic Assistance Program No. 13.77-3, Medicare Hospital Insurance and No. 13.774, Supplementary Medical Insurance)

Dated: April 22, 1987.

William L. Roper,

Administrator, Health Care Financing Administration.

Approved: June 11, 1987.

Otis R. Bowen,

Secretary.

Editorial Note.—This document was received at the Office of the Federal Register February 25, 1988.

[FR Doc. 88-4383 Filed 3-1-88; 8:45 am]

BILLING CODE 4120-01-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 67

[Docket No. FEMA-6920]

Proposed Flood Elevation Determinations, Correction

AGENCY: Federal Emergency Management Agency.

ACTION: Proposed rule; correction.

SUMMARY: This document corrects a Notice of Proposed Determinations of base (100-year) flood elevations previously published at 52 FR 46789 on December 10, 1987. This correction notice provides a more accurate representation of the Flood Insurance Study and Flood Insurance Rate Map for the Unincorporated Areas of Dickinson County, Kansas.

FOR FURTHER INFORMATION CONTACT: Mr. John L. Matticks, Chief, Risk Studies Division, Federal Insurance Administration, Federal Emergency Management Agency, Washington, DC 20472 (202) 646-2767.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency gives notice of the correction to the Notice of Proposed Determinations of base (100-year) flood elevations for selected locations in the Unincorporated Areas of Dickinson County, Kansas, previously published at 52 FR 46789 of December 10, 1987, in accordance with Section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448)), 42 U.S.C. 4001-4128, and 44 CFR 67.4(a).

List of Subjects in 44 CFR Part 67

Flood Insurance, Floodplains.

The proposed base (100-year) flood elevations for selected locations are:

PROPOSED BASE (100-YEAR) FLOOD ELEVATIONS

Source of Flooding and Location	#Depth in feet above ground. Elevation in feet (NGVD)
Smoky Hill River:	
About 1.44 miles downstream of State Highway 206	*1110
About 2.6 miles upstream of County Highway 186	*1173
Chapman Creek:	
At mouth	*1110
About 3.3 miles upstream of Union Pacific railroad	*1116
Mud Creek:	
At mouth	*1148
Just downstream of U.S. Highway 40 and Interstate 70	*1167
Mud Creek Tributary #1:	
At mouth	*1159
About 0.4 mile upstream of Atchison, Topeka and Santa Fe Railway	*1176
Solomon River:	
At mouth	*1170
About 700 feet upstream of confluence of Solomon River Tributary	*1171
Solomon River Tributary:	
At mouth	*1171
About 0.78 mile upstream of 7th Street	*1189

PROPOSED BASE (100-YEAR) FLOOD ELEVATIONS—Continued

Source of Flooding and Location	#Depth in feet above ground. Elevation in feet (NGVD)
Lyon Creek:	
At county boundary	*1147
Just downstream of Lyon Creek Dam No. 6	*1306
Just upstream of Lyon Creek Dam No. 6	*1344
About 0.27 mile upstream of Oklahoma, Kansas, and Texas Railroad	*1344
Carry Creek:	
Just upstream of mouth	*1146
About 4.07 miles upstream of State Highway 209	*1293
West Branch Lyon Creek:	
At mouth	*1222
About 11.08 miles upstream of State Highway 218	*1313
Lime Creek:	
At mouth	*1253
About 1.15 miles upstream of U.S. Highway 77 and 56	*1363
Lime Creek Tributary No. 2:	
At mouth	*1315
Just downstream of U.S. Highway 77	*1344
Just upstream of U.S. Highway 77	*1351
Lime Creek Tributary No. 4:	
At mouth	*1325
Just downstream of Oklahoma, Kansas, and Texas Railroad	*1341
Turkey Creek:	
At mouth	*1143
At confluence of East and West Turkey Creeks	*1257
West Branch Turkey Creek:	
At mouth	*1180
About 2.36 miles upstream of State Highway 15	*1253
Turkey Creek Tributary No. 1:	
At mouth	*1240
At State Highway 4	*1282
Turkey Creek Tributary No. 2:	
At mouth	*1244
About 0.45 mile upstream of Union Pacific railroad	*1263
West Turkey Creek:	
At mouth	*1257
About 1.97 miles upstream of confluence of Middle Branch Turkey Creek	*1337
East Turkey Creek:	
At mouth	*1257
About 2.0 miles upstream of confluence of East Turkey Creek Tributary No. 5	*1316
Middle Branch Turkey Creek:	
At mouth	*1318
At county boundary	*1324
East Turkey Creek Tributary No. 1:	
At mouth	*1278
About 2.97 miles upstream of confluence of East Turkey Creek Tributary No. 2	*1324
East Turkey Creek Tributary No. 2:	
At mouth	*1286
Just downstream of Turkey Creek Dam No. 8	*1297
East Turkey Reservoir No. 6: Along Shoreline	*1343
East Turkey Reservoir No. 5: Along Shoreline	*1339
East Turkey Reservoir No. 4: Along Shoreline	*1301
Turkey Reservoir No. 3: Along Shoreline	*1296
Turkey Reservoir No. 8: Along Shoreline	*1318
Turkey Reservoir No. 11: Along Shoreline	*1384
Turkey Reservoir No. 13: Along Shoreline	*1305
Turkey Reservoir No. 12: Along Shoreline	*1314
Turkey Reservoir No. 1: Along Shoreline	*1259
Turkey Reservoir No. 14: Along Shoreline	*1259
Turkey Reservoir No. 2: Along Shoreline	*1236
Lime Reservoir No. 3: Along Shoreline	*1401
Lyon Reservoir No. 6: Along Shoreline	*1344
Lyon Reservoir No. 12: Along Shoreline	*1300
Lyon Reservoir No. 13: Along Shoreline	*1282
Lime Reservoir No. 11: Along Shoreline	*1301
Lime Reservoir No. 10: Along Shoreline	*1308
Lyon Reservoir No. 7: Along Shoreline	*1314
Lyon Reservoir No. 14: Along Shoreline	*1285
Carry Reservoir No. 16: Along Shoreline	*1253
Lime Reservoir No. 4: Along Shoreline	*1346